

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

**IN RE: TYLENOL
(ACETAMINOPHEN) MARKETING,
SALES PRACTICES, AND
PRODUCTS LIABILITY
LITIGATION**

§ **MDL NO. 2436**
§
§ **2:13-md-02436**
§
§ **HON. LAWRENCE F. STENGEL**

This Document Relates to:

Rana Terry, as Personal Representative
and Administrator of the Estate of Denice
Hayes, Deceased,

Plaintiff,

vs.

McNEIL-PPC, Inc., McNeil Consumer
Healthcare, and Johnson & Johnson, Inc.,

Defendants.

Civil Action No. 2:12-cv-07263

M E M O R A N D U M

Stengel, J.

July 27, 2016

This case is part of a Multidistrict Litigation (MDL) involving claims of liver damage from the use of Tylenol at or just above the recommended dosage.¹ This is the

¹ See Master Compl., 13-md-2436, Doc. No. 32. There are close to two hundred other cases included in this MDL, along with several similar cases in New Jersey state court.

first “bellwether” case scheduled for trial.² The defendants move to exclude certain opinions of plaintiff’s specific causation expert, Craig E. Smith, M.D. The plaintiff plans to call Dr. Smith to testify about Ms. Hayes’ cause of death.³ For the reasons explained below, I will deny this Daubert motion.

I. LEGAL STANDARD

The admissibility of expert testimony is governed by Federal Rules of Evidence 702 and 703 as well as by Daubert v. Merrell Dow Pharmas., Inc., 509 U.S. 579 (1993), and its progeny.⁴ See In re Paoli RR Yard PCB Litigation (Paoli II), 35 F.3d 717, 735 (3d Cir. 1994). “Under the Federal Rules of Evidence, a trial judge acts as a ‘gatekeeper’ to ensure that ‘any and all expert testimony or evidence is not only relevant, but also reliable.’” Pineda v. Ford Motor Co., 520 F.3d 237, 243 (3d Cir. 2008)(quoting Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802, 806 (3d Cir. 1997)). The Third Circuit recognizes a “liberal policy of admissibility” regarding Rule 702. Pineda, 520 F.3d at 243 (quoting Kannankeril, 128 F.3d at 806); United States v. Schiff, 602 F.3d 152, 173 (3d Cir. 2010).⁵

² A “bellwether” case is a test case. “Bellwether” trials should produce representative verdicts and settlements. The parties can use these verdicts and settlements to gauge the strength of the common MDL claims to determine if a global resolution of the MDL is possible. See FEDERAL JUDICIAL CENTER, MANUAL FOR COMPLEX LITIGATION, FOURTH EDITION 360 (2004); DUKE LAW CENTER FOR JUDICIAL STUDIES, MDL STANDARDS AND BEST PRACTICES 16-21 (2014).

³ See Expert Report of Craig Smith, M.D. (Doc. No. 114, Def. Ex. A).

⁴ Daubert held that the Federal Rules of Evidence, specifically Rule 702, controlled the issue of when experts were qualified. Daubert v. Merrell Dow Pharmas., Inc., 509 U.S. 579, 587-88 (1993). It found that Rule 702 superseded the Court’s prior precedent on the subject found in Frye v. United States, 54 App.D.C. 46, 47, 293 F. 1013, 1014 (1923). Id. at 587. Daubert went on to clarify what was required under Rule 702, as compared to Frye. See id. at 589-598.

⁵ See also Holbrook v. Lykes Brothers Steamship Company, Inc., 80 F.3d 777, 780 (3d Cir. 1996); Zaprala v. USI Servs. Gp., Inc., No. 09-1238, 2013 WL 1148335, at *6 (E.D. Pa. Mar. 20, 2013)(quoting Pineda, 520 F.3d at 243).

“[B]ecause expert evidence is often more misleading than other evidence, Rule 403 gives a judge more power over experts than over lay witnesses.” In re Paoli RR Yard PCB Litigation (Paoli II), 35 F.3d 717, 747 (3d Cir. 1994). However, “in order for a district court to exclude scientific evidence, there must be something particularly confusing about the scientific evidence at issue—something other than the general complexity of scientific evidence.” Id.

a. Rule 702

Federal Rule of Evidence 702 has three major requirements: 1) the expert must be qualified; 2) the expert must testify about matters requiring scientific, technical, or specialized knowledge; and 3) the testimony must assist the trier of fact.⁶ Pineda, 520 F.3d at 243 (citing Kannankeril, 128 F.3d at 806). 702’s inquiry should be a “flexible one.” Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 594 (1993).

i. Expert Must Be Qualified

An expert’s qualifications may include education, provided it is in a field related to the one in which the expert intends to testify. Fedor v. Freightliner, Inc.,

⁶ Federal Rule of Evidence 702 states:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

193 F. Supp. 2d 820, 827 (E.D. Pa. 2002). Overall, the court will consider both academic training and practical experience to determine if the expert has “more knowledge than the average lay person” on the subject. Id. at 827-28 (citing Waldorf v. Shuta, 142 F.3d 601, 627 (3d Cir. 1998)). “An expert may be generally qualified but may lack qualifications to testify outside his area of expertise.” Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 322 (3d Cir. 2003).

However, this does not mean that the “best qualified” expert must testify. “[W]itnesses may be competent to testify as experts even though they may not, in the court's eyes, be the ‘best’ qualified.” Holbrook v. Lykes Bros. S.S. Co., Inc., 80 F.3d 777, 782 (3d Cir. 1995).⁷ “Rule 702 and Daubert put their faith in an adversary system designed to expose flawed expertise.” U.S. v. Mitchell, 365 F.3d 215, 244-45 (3d Cir. 2004)(citations omitted). “As long as an expert's scientific testimony rests upon ‘good grounds, based on what is known,’ it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.” Id. at 244 (citations omitted).

ii. Expert's Methods Must be Reliable

This Circuit interprets the second factor as one of “reliability,” i.e., the testimony is admissible so long as the process or technique the expert used in formulating the

⁷ See also Keller v. Feasterville Family Health Care, 557 F. Supp. 2d 671, 675 (E.D. Pa. 2008)(Rice, J.).

opinion is reliable. Pineda, 520 F.3d at 244. An expert's opinion need not be correct, only reliable. See In re Paoli RR Yard PCB Litigation (Paoli II), 35 F.3d 717, 744 (3d Cir. 1994)(“This does not mean that plaintiffs have to prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.” (emphasis in original)). “[A]n expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation.” Daubert, 509 U.S. at 592. “[I]t is the burden of the party offering the expert scientific testimony to demonstrate reliability by a preponderance of the evidence.” In re TMI Litig., 193 F.3d 613, 705 (3d Cir. 1999)(citing Paoli II, 35 F.3d at 744).⁸

“Rule 702 grants the district judge the discretionary authority, reviewable for its abuse, to determine reliability in light of the particular facts and circumstances of the particular case.” Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 158 (1999). Judges considering this factor should look to whether a theory, technique, or opinion can be tested or has been subject to peer review or publication. Daubert, 509 U.S. at 593. “The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.” Id. at 594. A court should also consider the known or potential rate of error involved in a scientific method. Id.

⁸ See also FED. R. EVID. 702, Advisory Committee Note (2000 Amendments)(“Under that Rule, the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence.” (citing Bourjaily v. United States, 483 U.S. 171 (1987))).

“Reliability” does not require that a technique or methodology be generally accepted by a scientific community. *Id.* See also *id.* at 597-98. However, “[w]idespread acceptance can be an important factor in ruling particular evidence admissible” while a minimally supported technique “may properly be viewed with skepticism.” *Id.*

iii. Expert Must be Helpful

The third factor “is typically understood in terms of whether there is a sufficient ‘fit’ between the expert’s testimony and the facts that the jury is being asked to consider.” *United States v. Schiff*, 602 F.3d 152, 172-73 (3d Cir. 2010)(citing *Daubert*, 509 U.S. at 591). See also *In re: TMI Litigation*, 193 F.3d 613, 670 (3d Cir. 1999). This factor is about relevance. “Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *Daubert*, 509 U.S. at 591 (quoting 3 Weinstein & Berger ¶ 702[02], p. 702–18). “Rule 702’s ‘helpfulness’ standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.” *Id.* at 591-92.

b. Rule 703

Under Federal Rule of Evidence 703, the data underlying the expert’s opinion is the central focus. Rule 703 states:

An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

FED. R. EVID. 703. The trial court must evaluate whether the data used by an expert is reasonably relied upon by experts in the field. See In re Paoli RR Yard PCB Litigation (Paoli II), 35 F.3d 717, 747-49 (3d Cir. 1994).

II. Dr. Smith is Qualified to Render an Opinion about Acetaminophen-Induced ALF as Cause of Death

First, the defendants contend that Dr. Smith is not qualified to offer an opinion that Ms. Hayes' cause of death was acetaminophen-induced acute liver failure (ALF) because he is not a liver specialist. They concede that Dr. Smith is an expert in infectious diseases and do not challenge his opinion about whether Ms. Hayes died of an infectious disease or sepsis. The plaintiff counters that Dr. Smith is qualified to diagnose Ms. Hayes' cause of death given his education and experience working with patients who have experienced both acetaminophen-induced ALF and sepsis (along with other etiologies).

An expert is considered "qualified" if he/she has "more knowledge than the average lay person" on the subject. Fedor v. Freightliner, Inc., 193 F. Supp. 2d 820, 827-28 (E.D. Pa. 2002)(citing Waldorf v. Shuta, 142 F.3d 601, 627 (3d Cir. 1998)). An expert's qualifications may include credentials gained from both formal education and practical experience. See id. at 827. Expert witnesses have to be qualified to testify. However, this does not mean that the court should only allow the "best qualified" expert to testify. See Holbrook v. Lykes Bros. S.S. Co., Inc., 80 F.3d 777, 782 (3d Cir. 1995). Instead, any weaknesses in the expert's background that may render his opinion less credible should be brought out during

cross-examination. See U.S. v. Mitchell, 365 F.3d 215, 244-45 (3d Cir. 2004)(citations omitted).

Dr. Smith is a medical doctor board-certified in both internal medicine and infectious diseases.⁹ He has served as the Director of Inpatient Medicine at Atlanta Medical Center, Medical Director at Phoebe Putnam Memorial Hospital, and Medical Director (Infectious Diseases) at University Hospital in Augusta, GA. Dr. Smith is the current Deputy Chief of Medicine at Charlie Norwood VA Medical Center in Augusta. He has served as a professor of medicine for medical students and supervised resident physicians.¹⁰ In addition, he has received education and training in acetaminophen toxicity.

During his forty (40) or so years as a physician, Dr. Smith has treated about twenty patients with acetaminophen-induced ALF.¹¹ He is familiar with the symptoms of acetaminophen-induced ALF and how to treat it with the antidote. During his experience as a treating physician, Dr. Smith has prepared adverse event reports for the FDA and poison control centers.¹² He has also served on numerous pharmacy committees at various hospitals which monitored side effects of the hospital's dispensation of drugs such as acetaminophen.¹³

⁹ See Curriculum Vitae for Craig Smith, M.D. (Pl. Ex. A) for information contained in this paragraph. See also C. Smith Dep., Apr. 17, 2015 at 6-33 (Doc. No. 114, Def. Ex. B) for an explanation of Dr. Smith's qualifications.

¹⁰ See C. Smith Dep., Apr. 17, 2015 at 260-61 (Doc. No. 114, Def. Ex. B).

¹¹ See id. at 106-111.

¹² See id. at 111.

¹³ See id. at 116.

I find that Dr. Smith is qualified to offer an opinion about whether acetaminophen-induced ALF, as opposed to sepsis, was the cause of Ms. Hayes' death. He is an internal medicine physician who has worked in hospitals for almost forty years. He continues to oversee treating physicians and has had experience treating patients experiencing acetaminophen-induced ALF. He meets the requirements of prong 1 of Rule 702 and Daubert.

III. Dr. Smith's Methods are Reliable

Next, the defendants take aim at Dr. Smith's methodology, claiming it is unreliable. Dr. Smith uses "differential diagnosis" in analyzing the decedent's cause of death. This methodology is typically what he and other doctors use in determining what treatment is required for patients.¹⁴ They review their patients' medical records, lab data, etc. to determine what the cause of their conditions would be.¹⁵ This is the methodology Dr. Smith was trained to use and which he trains medical students to use.¹⁶ From what has been provided, this methodology is generally accepted and used by the medical community. Dr. Smith's analysis rests on "good grounds."¹⁷ I find it to be reliable.

¹⁴ See C. Smith Dep., Apr. 17, 2015 at 59-68, 251-53 (Doc. No. 114, Def. Ex. B).

¹⁵ See id. at 59-68, 250-53. The plaintiff also noted in her brief that the lab data to which Dr. Smith cited in reaching the conclusion that Ms. Hayes died of acetaminophen-induced ALF was the same data that hepatologists looked at in drawing the same conclusion.

¹⁶ See C. Smith Dep., Apr. 17, 2015 at 250-51 (Doc. No. 114, Def. Ex. B).

¹⁷ See U.S. v. Mitchell, 365 F.3d 215, 244 (3d Cir. 2004)(citations omitted) ("As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies."); Holbrook v. Lykes Bros. S.S. Co., Inc., 80 F.3d 777, 784 (3d Cir. 1995) ("The reliability requirement, however, should not be applied too strictly."); *id.* ("If the expert has 'good grounds' for the testimony, the scientific evidence is deemed sufficiently reliable.").

The defendants also take issue with Dr. Smith's inability to offer an opinion about dosing. They claim he would not be qualified or his methodology unreliable because he could not render an opinion about what dose of acetaminophen Ms. Hayes took to cause her ALF. See In re: Diet Drugs (Phentermine, Fenfluramine,Dexfenfluramine) Prods. Liab. Lit., No. MDL 1203, 2000 WL 876900, at *6 (E.D. Pa. June 20, 2000)(“A court should ‘exclude proffered expert testimony if the subject of the testimony lies outside the witness’s area of expertise.’”)(quoting 4 WEINSTEIN’S FED. EVID. § 702.06[1], at 702-52 (2000)). The defendants point out that Dr. Smith could not determine from the lab data whether Ms. Hayes’ serum level was possible at the recommended dose of acetaminophen. Dr. Smith admits he’d have to refer to other experts’ opinions on this point. I do not see his inability to answer this specific question as rendering him unqualified to offer an opinion about Ms. Hayes’ cause of death. What dose Ms. Hayes took is a different question from whether acetaminophen-induced ALF caused her death (and whether sepsis did not).

IV. Dr. Smith Can Offer Observations Related to Warnings, Labels, and Advertising, If the Defendants “Open the Door” to this Line of Questioning

Lastly, the defendants argue that Dr. Smith’s opinions concerning Tylenol labels, warnings, and advertisements are inadmissible because these opinions were not contained in his expert report, he is not qualified to offer them, and the opinions are improper under Rules 702 and 403.¹⁸ In response, the plaintiff points to the context of those opinions,

¹⁸ See C. Smith Dep., Apr. 17, 2015 at 119-20, 253-57, 263-65 (Doc. No. 114, Def. Ex. B).

being that of rebuttal to the defendants' line of questioning about whether it was foreseeable that patients would misuse Tylenol. They argue that the defendants shouldn't "open the door" to such line of questioning at trial and then expect Dr. Smith to be precluded from sharing his observations on the subject. I agree that this testimony is permissible if the defendants "open the door," which appears to have been done in the deposition. Otherwise, Dr. Smith's expert opinions about Tylenol advertising and whether the warning labels were adequate would not be admissible because he is not qualified to offer opinions in this area.

V. CONCLUSION

For the above reasons, I will **DENY** the defendants' Daubert motion to exclude certain opinions of Dr. Craig Smith **without prejudice**.

An appropriate Order follows.